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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,430

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Magnus Ohman

P05,0115

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26574

7590

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EXAMINER

PATTON, AMANDA K

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,430	<b>Applicant(s)</b> OHMAN ET AL.	
	<b>Examiner</b> Amanda Patton	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-17 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 19-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. However, this action has been made final as necessitated by the amendments to the claims presented August 27, 2007, wherein the claims were amended in response to the first Office action dated July 16, 2007. Currently claims 14-17 and 19-29 are pending in this application.

Applicant's arguments dated December 31, 2008 with respect to the rejection(s) of claim 14 (previously claim 18) under 35 U.S.C. 103(a) over Gilli in view of Levine have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Ujhelyi (USPN 6,813,516) in view of Levine.

### ***Claim Objections***

Claims 15-17 and 19 are objected to because of the following informalities. Appropriate correction is required.

Regarding **claims 15-17**, claim 15 recites the phrase "wherein said control unit switches said pacing pulse generator back to said first mode after a predetermined time interval". It is unclear if this is the same time interval as the "extended time interval" of claim 14. If Applicant is trying to claim an initial predetermined time interval followed by an optional extension of time (as more clearly spelled out in claim 19), such limitations should be included in the claims as supported by the specification.

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Regarding **claim 19**, the phrase "said extendable time interval" as it is unclear if this is the same or different time interval as the "extended time interval" of claim 14.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17, 19-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ujhelyi et al. (USPN 6,813,516) in view of Levine (USPN 6,430,441, as previously cited).

Regarding **claims 14-15, and 19-20**, Ujhelyi discloses the claimed invention including: a pacing pulse generator (e.g. as show in Figure 1); a high energy pulse generator configured to deliver a defibrillation shock (e.g. defibrillation circuit 140); sensing circuitry configured to interact with the heart to sense intrinsic cardiac activity resulting from capture following a delivered pacing pulse (e.g. sense amp A 122 and sense amp V 144); and a control unit connected to the pacing pulse generator (e.g. control 106), wherein the control unit normally operates in a first mode (e.g. a DDD, DVI, VDD, DDI "normal" pacing mode; Col. 4, lines 36-42), and that automatically switches from operating in a first mode to operating in a second mode following the delivery of a shock (e.g. step 206-208 of Figure 2 wherein the second mode is a DDI mode of pacing followed by an AAI overdrive pacing mode, and thus has predetermined settings, such as a pacing rate above the intrinsic heart rate between 500ms and 100ms; Col. 5,

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lines 19-34), and the sensing circuitry as configured to measure signal characteristics of the sensed cardiac activity signal following the shock (e.g. step 210 that detects a re-occurrence of atrial fibrillation), and wherein the control unit is configured to switch the pacemaker back to the first mode following an extended time interval (e.g. Col. 5, lines 43-45; step 212), wherein the time period is extended by the control unit dependent on the characteristics of the sensed cardiac activity following the shock (e.g. if an atrial fibrillation episode is detected at step 210 the overdrive pacing is reinitiated, and thus the second mode is extended). As the claim is a comprising claim it does not preclude other shocks to occur during the second mode of pacing operation.

Ujhelyi does not disclose a first mode that includes an autocapture mode. Levine discloses that it was well known in the art to normally operate a pacing pulse generator in an autocapture mode (e.g. Abstract). It would have been obvious to one having ordinary skill in the art to replace the first “normal” mode of Ujhelyi with an autocapture mode, since such modes are well known in the art for providing the system with the ability to only apply pacing when necessary at the lowest stimulation level possible for providing the predictable results of reducing battery depletion.

Examiner wishes to note that the addition of the phrase “and, in said second mode, said control unit operating said pacing pulse generator with predetermined settings for said pacing pulses” to the independent claim does not preclude the second mode to operate in an autocapture mode, as the “predetermined setting” could include operation in an autocapture mode. If Applicant wishes to claim more specific requirements for the second mode of operation, such limitations should be inserted in the claims as supported by the specification.

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Regarding **claims 16, 17, and 21-24**, Ujhelyi and Levine does not expressly teach time intervals of the second mode of pacing in the range: between one minute and fifteen minutes (claims 16 and 23), between five minutes and ten minutes (claims 17 and 24), between five minutes and fifteen minutes (claim 21), and approximately 10 minutes (claim 22). However, Ujhelyi discloses that the second mode should not exceed 10 minutes (Col. 3 line 28), which is a point in all of the above ranges, and thus anticipates the range.

Regarding **claim 25**, Ujhelyi does not expressly disclose extending the time interval based on an amplitude of the cardiac activity signal. It is well known in the art, however, that AF results in the loss of recognizable P-wave, which is based on an amplitude of the cardiac activity signal. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the amplitude of the cardiac activity signal to determine an AF episode and subsequently extend the time period, since such a modification would provide the system with a reliable way to determine an AF episode.

Regarding **claims 26-29**, Ujhelyi discloses delivering pacing pulses to an atrium and a ventricle of the heart (e.g. pacing in a DDD mode) and defibrillation to an atrium or a ventricle of the heart (e.g. Col. 4, lines 42-58).

### ***Response to Arguments***

Applicant's arguments with respect to claims 14-17 and 19-29 have been considered but are moot in view of the new ground(s) of rejection. Examiner again wishes to note that the claims as presently filed do not exclude the second mode from operating in an autocapture mode, as the "predetermined setting" could include operation in an autocapture mode. If Applicant wishes to

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claim more specific requirements for the second mode of operation, such limitations should be inserted in the claims as supported by the specification.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/  
Examiner, Art Unit 3762

/George R Evanisko/  
Primary Examiner, Art Unit 3762